Remarks

Claims 21, 24-26, 29, and 32-34 are pending. Claims 1-20, 22, 23, 27, 28, 30, 31, 35, and 36 are cancelled.

The final Office Action mailed February 20, 2009 rejects each of the pending claims 21, 24-26, 29, and 32-34. Specifically, claims 21, 22, 24-30, and 32-36 are rejected under §103(a) as obvious over **Patel et al** (WO 01/37808) in view of **Alford** (US 3,937,825) or **Jans et al.** (5,824,336).

With the present Amendment and Reply, Applicants amend claims 21 and 29 to recite a compatible cationic polymer matrix and additional cationic masking protective layer, respectively. Support for this amendment is found throughout the specification including, but not limited to, paragraph [0118] of the published specification (US 2005/0169971).

Claims 24 and 32 are amended to recite that the physiologically compatible cationic polymer matrix is an acrylic acid polymer or a methacrylic acid polymer or a combination of these polymers. New claims 42 and 48 are also introduced to recite the same. Support for this amendment is found throughout the specification including, but not limited to, paragraphs [0117] and [0118] of the published specification.

New independent claims 41 and 47 are introduced and differ from the existing independent claims 21 and 29 by reciting a pH-dependency for the "second coat" and "masking protective layer," respectively. Support for this amendment is found throughout the specification including, but not limited to, paragraph [0118] of the published specification.

New claims 37, 39, 45, and 51 are introduced and recite a particle size of 0.15-0.4 mm. Support for this amendment is found throughout the specification including, but not limited to, paragraphs [0104] and [0126] of the published specification.

New claims 38, 40, 46, and 52 are introduced and recite that the cationic polymer is based on dimethylaminoethyl methacrylate and neutral methacrylic esters. Support for this amendment is found throughout the specification including, but not limited to, paragraph [0118] of the published specification.

New claims 43 and 49 are also introduced to recite additives in the composition and the step of adding one or more additives, respectively. Support for this amendment is found throughout the specification including, but not limited to, paragraph [0134] of the published specification.

New claims 44 and 50 are also introduced to recite that the substrate is yeast. Support for this amendment is found throughout the specification including, but not limited to, paragraph [0123] of the published specification.

No new matter is presented. Continued examination of the claims is earnestly solicited.

Rejection of Claims 21, 24-36, 29, and 32-34 Under 35 USC §103

As noted above, the Examiner rejects claims 21, 24-26, 29, and 32-34 under §103(a) as obvious over **Patel et al** (WO 01/37808) in view of **Alford** (US 3,937,825) or **Jans et al** (5,824,336). The Examiner contends that **Patel et al** provide the coated instant particles, inclusive of benzepril over sugar or lactose or starch of 30-35 mesh size. The Examiner relies on **Alford** and **Jans et al** to allegedly show how the coated particles can be mixed with animal feed substrate and pelleted.

The present invention is concerned with a composition in pellet or tablet form for use in administering medicines to animal as a part of feed consumption. Specifically, the present application provides an intimate mixture of (i) animal feed, for example yeast; and (ii) particles of a **specific** size which are coated -- first with benazepril and second with a second coat or masking protective layer. In this manner, the overall composition may be ingested, as feed consumption, without exposing the bitter-tasting active ingredient to the gustatory cells of the animal's mouth.

The Examiner cites *KSR*, but fails to appreciate a key component of the Supreme Court's reasoning in *KSR* is that the information in KSR's prior art yielded predictable results.

> A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex,* 82 USPQ2d 1385.

In this case, there is absolutely no reasonable expectation of success from the cited references.

Patel et al disclose a pharmaceutical composition for use in humans. The final product may be swallowed – and there is no appreciation or discussion of a composition subject to breakage during consumption. **Patel et al** disclose particles that are coated with an active ingredient. Mixtures of said particles with an animal feed substrate, such as yeast, are not proposed or disclosed anywhere. Thus, the particle size, as claimed in the present invention, is of no concern at all in the **Patel et al** reference. Without a recognition of the problem to be solved, there can be no expectation of success in a solution.

Further, although benazepril is mentioned in the prior art document, there is no real focus on this specific drug, since it is only part of an immense list of all kinds of drugs

(emphasis added). **Patel et al**, by no means, provide a motivation to select a benazepril formulation. Further, there is no appreciation in the **Patel et al** reference of the pronounced bitter taste of benazepril and its use in veterinary applications. Moreover, without such appreciation there can be no suggestion for the need to make benazepril appealing to animals for feed consumption.

In addition, the **Patel et al** composition actually teaches away from the present invention. **Patel et al** requires particles to be coated with a combination of active ingredient and a hydrophilic surfactant. Please refer to the extensive disclosure of surfactants in the **Patel et al** reference. In strong contradiction thereto, the particles of the present invention are coated with the active ingredient, alone, and are then further protected by a second, discrete layer.

Embodiments of the presently claimed invention represent successful commercial animal health products around the world. The commercial product provides needed medicines to cats (renal insufficiency) and dogs (congestive heart failure) in a form (feed) acceptable to the animals. **Patel et al** is in a different technical field, namely dealing with human drugs in general without regard to compliance due to taste. **Patel et al** provides no motivation to mask bitter tasting drugs that would be subjected to breakage and exposure within the mouth. Accordingly, **Patel et al** fails as a starting point for an argument of prima facie obviousness.

The secondary references are insufficient to cure the deficiencies of the primary reference. Similar to **Patel et al**, **Alford** does not propose, teach or suggest the concept of mixing a feed substrate with drug coated particles. Further, **Alford** fails to recognize the unique problems associated with the specific active ingredient, benazepril, the specific size of the particles, or their specific coating. **Jans et al** disclose a composition containing flubendazole, useful for the treatment of helminthiasis in companion animals (see column 1, lines 44-47). Contrary to the presently claimed composition and method of making an animal medicament, **Jans et al** disclose preparing compositions by simply mixing the ingredients or by blending the active, flubendazole, with the suitable excipients and granulating the blend, each of which include the addition of yeast (see column 3, lines 21-25). If these yeast cells are mixed with an extremely bitter active ingredient, such as benazepril, prior to compressing into tablets, the targeted animal (e.g., cat) quickly crunches it, spits it out and turns away in disgust (see instant published specification –paragraph [0096]). Thus, **Jans et al** and **Alford** do not even remotely teach or suggest and, by failing to recognize the problems of benazepril, teach away from the instantly claimed composition

or method of making the animal medicament. The cited secondary references cannot cure the deficiencies of **Patel et al**.

Accordingly, the presently claimed invention is not rendered obvious even by a combination of two or more of the cited references. None of the cited references discloses the specific structure of the inventive composition, including the size range and recognition of the particular bitter component. Applicants request withdrawal of the §103(a) rejection.

Applicants believe the present claims are in condition for allowance and respectfully request such action. If the Examiner has any remaining issues for resolution, he is encouraged to telephone the undersigned for expeditious handling.

Respectfully submitted,

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